## **EXHIBIT 19**

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 303-D
200 Independence Avenue, SW
Washington, DC 20201



**Public Affairs Office** 

## **MEDICARE NEWS**

FOR IMMEDIATE RELEASE Tuesday, July 27, 2004

Contact: CMS Public Affairs Office (202) 690-6145

## MEDICARE PROPOSES PAYMENT RULE TO PROVIDE NEW PREVENTIVE BENEFITS AND RAISE PHYSICIAN PAYMENTS FOR 2005

As part of its ongoing efforts to modernize Medicare, the Centers for Medicare & Medicaid Services (CMS) today proposed new benefits to help Medicare beneficiaries stay healthier and get better access to important preventive medical services, as well as to implement an across the board 1.5 percent increase in payment rates for physicians taking care of Medicare beneficiaries.

The new payments are part of the agency's Physician Fee Schedule rule for 2005.

The new preventive benefits, which were authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), are the heart of the initiative to make Medicare a modern prevention-focused program.

"When it comes to modern health care Medicare had it backwards, spending 99 percent of its resources treating seniors after they got sick and only 1 percent on preventing illness and promoting wellness," said Health and Human Services Secretary Tommy Thompson. "With this new law, we are reversing this trend and focusing Medicare more on disease prevention and management."

"I know how important it is to have not only good coverage for preventive tests to get better outcomes, but also coverage that provides access to high-quality physician services," said CMS Administrator Mark B. McClellan, M.D., Ph.D.

Central to the initiative is the "Welcome to Medicare Physical," an initial preventive examination for all new Medicare beneficiaries. This benefit is particularly important since, according to the Medicare Current Beneficiary Survey, many Medicare beneficiaries do not receive recommended mammograms, pap tests, prostrate screening, flu shots, or pneumonia shots because "they didn't know it was needed."

While colorectal cancer kills 56,000 people a year, 56 percent of Americans 50 and older have not made use of screening tests that can detect it at an early, treatable stage.

The proposed rule also provides new Medicare coverage for cardiovascular screening blood tests for the detection of cardiovascular disease or related abnormalities and coverage for diabetes screening tests for beneficiaries identified as at-risk for this illness.

Additionally, the proposal will reduce health care costs for beneficiaries. New changes in drug and drug administration payments, designed to make sure Medicare pays appropriately for new drugs and their administration, would reduce beneficiary spending. Combined with changes in the Part B deductible and in beneficiary coinsurance for 2005 that increase spending, beneficiaries will experience a net savings of \$270 million.

"Medicare will have the most comprehensive array of preventive benefits ever – including coverage of a Welcome to Medicare exam and screening for heart disease, diabetes, weak bones, and cancers of the colon, breast, cervix, and prostate, as well as vaccinations for influenza, pneumonia, and hepatitis B," McClellan said.

"We now cover preventive care for the serious illnesses whose complications account for most of Medicare costs today – complications that can often be prevented with early diagnosis and treatments including drugs," McClellan said. "We intend to use these new benefits to re-direct Medicare to become a truly prevention-focused program."

Total Medicare spending for more than 875,000 physicians and other health care professionals will increase by more than 4 percent from a projected \$52.7 billion in 2004 to a projected \$55.0 billion in 2005. The payment increases reflect a provision in the MMA that substituted a set payment update of 1.5 percent in 2004 and 2005, effectively avoiding a projected update of minus 3.7 percent for 2005 under previous law.

At the same time, the rule takes many further steps to improve access to highquality care, including:

New incentive payments to doctors practicing in physician scarcity areas. These payments of 5 percent would be made to both primary care and specialty physicians furnishing services to beneficiaries in the areas with the lowest 20 percent of physician to beneficiary ratios.

- New telehealth billing for most monthly management services furnished to beneficiaries on dialysis. By allowing physicians to make visits using telecommunications equipment, CMS believes that rural patients with ESRD will have greater access to care.
- Expanded beneficiary access to a broader array of health care professionals. For example, the proposed rule would authorize psychologists to receive payment for both administering diagnostic psychological tests and for supervising the administration of these tests.
- A clarification that Medicare will pay for care plan oversight for beneficiaries
  receiving home health care when this oversight is provided by non-physician
  professionals, including nurse practitioners, physician assistants, and clinical
  nurse specialists, if authorized by State law to provide these services.
- New coverage for a one-time evaluation and counseling from a physician employed by a hospice to determine appropriate end-of-life services for terminally ill beneficiaries.

The proposed rule would also give beneficiaries more access to state-of-the-art treatments. For example, it removes restrictions on payment for higher-cost low osmolar contrast materials (LOCM). These materials, which are used to enhance the results of x-rays and other radiological procedures, present less risk of complications such as flushing, anxiety, nausea, and vomiting. Although LOCM is more expensive than other contrast materials, Medicare recognizes that its use has become standard practice among radiologists. As another example, Medicare will begin covering routine clinical costs in studies of certain potentially life-saving investigational devices.

The proposed rule is also an important step in implementing changes in law to improve the accuracy of Medicare's payments for Part B-covered drugs and the critical administration services that these drugs require.

"When Medicare has regulated drug prices, too often the prices have been much higher than the best competitive market prices, resulting in potentially excessive spending by Medicare and beneficiaries," said Dr. McClellan. "We now have new tools to pay appropriately for each drug as well as the valuable services that go along with administering drugs, rather than having an overpayment for one subsidize an underpayment for the other."

Under the MMA, the standard payment rate for most Part B drugs will be set at 106 percent of the average sales price (ASP). With the proposed regulation, CMS is releasing its initial, preliminary data on ASP for 32 widely used Part B drugs.

CMS is releasing these early data for purposes of comment only. CMS expects that comments on these preliminary data and subsequent data submissions will improve methods for ASP data collection and reporting. Data from subsequent reports will be used as a basis for the final drug payment rates. In conjunction with the review of comments on appropriate changes in payments for services associated with drug administration, the comments and improved data will help ensure that patients continue to get access to the Part B drugs and services they need while eliminating overpayments.

The rule will implement MMA changes that affect payment rates for drugs that are used to treat respiratory disorders such as chronic obstructive pulmonary disease. Before the MMA, Medicare only covered these drugs when delivered through one type of device, a special machine called a nebulizer. Two of these drugs – albuterol sulfate and ipratroprium bromide – are currently paid at 80 percent of the average wholesale price (AWP), an amount that the Inspector General and the Government Accountability Office found to be grossly in excess of their actual acquisition cost. Under the MMA, the 2005 payment rate will be based on ASP.

Respiratory therapy drugs can also be delivered using metered dose inhalers (MDIs). These disposable devices that are less expensive, more portable, and faster and easier to use than nebulizers, but Medicare has not paid for them in the past. With the implementation of the Part D drug benefit in 2006, Medicare will begin to pay for inhalation drugs delivered by MDIs, including those with spacers and other new features that make them easier to use. In the interim, MDIs are available at discounted prices for Medicare beneficiaries who have enrolled in the Medicare discount card program.

"In addition to more affordable access to portable inhaler treatments, we intend to make sure that beneficiaries who need to use nebulizers have access to these drugs," said Dr. McClellan. "We are seeking comments on setting an appropriate dispensing fee that reflects the costs of the shipping, handling, compounding, and other pharmacy activities required to furnish inhalation drugs to Medicare beneficiaries."

The proposed rule also seeks comment on whether a transitional payment may be needed to prevent disruption of beneficiary access as these payment changes occur and before the Part D benefit takes effect. The rule also reduces the paperwork associated with billing for inhaled drugs, thus reducing the costs incurred by suppliers for furnishing these drugs.

CMS will also be seeking comments on implementing the provisions of the MMA to achieve more accurate Medicare payments for certain drugs and associated services provided in the physician office, particularly for cancer treatments.

The proposed rule includes payment rates for administering drugs that reflect oncologist survey data on the costs of running an oncology practice, and the rates will be more than 110 percent higher in 2005 than in 2003.

CMS has announced that Medicare will consider further changes to coding and payment for administering drugs based on a review being undertaken by the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel. This review will be completed later this summer and CMS will consider the panel's recommendations when determining final payment rates for 2005 later this year.

Based on very preliminary ASP data and these other changes, CMS is currently projecting a net reduction in total oncology Medicare revenues as a result of more accurate payment for drugs. However, these changes may be offset by such factors as the AMA CPT review and resulting changes in payments for services, improved data on drug prices. In addition, because spending on oncology services has been increasing by an average rate of 25 percent per year in recent years, utilization growth may also increase oncology payments in 2005.

The proposed rule makes a number of changes in how Medicare pays for services to beneficiaries with end-stage renal disease (ESRD). First, it would eliminate the cross-subsidy in payments for drugs used in ESRD treatment so that Medicare's payment reflects the acquisition costs of the drugs, while increasing payment rates for ESRD providers by the amount of the drug cross-subsidy.

Second, the proposed payment rates for ESRD facilities will for the first time be adjusted to reflect the higher costs of treating certain types of patients such as those with AIDS or with peripheral vascular disease. Payment rates will also be adjusted for factors such as age and gender.

While Medicare spending won't be affected as a result of these provisions, improved accuracy means that providers of ESRD care will be paid more fairly for the treatments required for the different types of patients, providing better financial incentives for appropriate care. Finally, ESRD facilities would receive a 1.6 percent update for services in 2005 under the proposal.

The proposed rule will be published in the August 5, 2004 Federal Register. Comments will be accepted until September 24. CMS plans to publish the final rule by November 1, with an effective date of January 1, 2005.